****** ********** NOTICE OF GRANT AWARD ********** **********
SMALL BUSINESS INNOVATION RESEARCH PROG Issue Date: 08/23/2002

Department of Health and Human Services
National Institutes Of Health

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
****

Grant Number: 1 R43 DK61164-01
Principal Investigator: HIRSCHMAN, GORDON B MENG
Project Title: Foot Pressure and Shear Data Visualization System

MCCAULEY, DOUGLAS
GENERAL MANAGER
FOSTER-MILLER TECHNOLOGIES, INC
431 NEW KARNER ROAD
ALBANY, NY 12205
UNITED STATES

DNIH. 030026

Budget Period: 09/01/2002 - 02/28/2003
Project Period: 09/01/2002 - 02/28/2003

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $119,415(see ''Award Calculation'' in Section I) to FOSTER-MILLER, INC. in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 15 USC 638 and is subject to terms and conditions referenced below.

Acceptance of this award including the Terms and Conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Award recipients are responsible for reporting inventions derived or reduced to practice in the performance of work under this grant. Rights to inventions vest with the grantee organization provided certain requirements are met and there is acknowledgement of NIH support. In addition, recipients must ensure that patent and license activities are consistent with their responsibility to make unique research resources developed under this award available to the scientific community, in accordance with NIH policy. For additional information, please visit http://www.iedison.gov.

If you have any questions about this award, please contact the individual(s) referenced in the information below.

Sincerely yours,

Kathleen J. Shino

Kathleen J. Shino
Grants Management Officer
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

See additional information below

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892

August 30, 2001

Reference: 1 R43 DK61164-01

Gordon B. Hirschman, MENGBS
Foster-Miller Technologies, Inc
431 New Karner Road
Albany, NY 12205

Dear Dr. Hirschman:

Enclosed is a copy of the summary statement prepared by the Scientific Review Administrator of the Initial Review Group (IRG) that evaluated your application. The budget figures shown on the Summary Statement may be subject to administrative adjustments. Funding decisions are based largely on the percentile ranking which is provided on the first page of most Summary Statements.

The National Diabetes and Digestive and Kidney Diseases Advisory Council will meet on **September 20-21, 2001**. Within 30 days after this meeting you will be notified by letter regarding the competitive position of your application with respect to the possibility of an award.

All applicants retain the right to appeal the IRG evaluation if there is evidence of a flawed review. An appeal letter must document scientific errors in the review or challenge the expertise of the Study Section. Any such appeals will receive Council review if received at least **two weeks** prior to the upcoming Council meeting. Should you plan to submit an appeal, you must contact this office immediately in order to discuss your concerns. We apologize for any inconvenience the short notice may entail; however, we are limited by the late date of the IRG review.

Please be aware that the NIH will not accept more than two revisions of a grant application (A2). In addition, the NIH will not accept a revised application that is submitted more than two years from the receipt date of the initial, unamended application. These new policies should be taken into consideration when planning the submission of a revised application.

The Division of Diabetes, Endocrinology, and Metabolic Diseases has reorganized its scientific programs to better address the research needs of our investigators and the Institute. As a result, the program director originally assigned to your application may have changed. The appropriate person to contact for your application is noted at the end of this letter.

If you should have any questions with regard to our procedures or your Summary Statement, please do not hesitate to contact me.

Sincerely,

for

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Enclosure

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SUMMARY STATEMENT
(Privileged Communication)

Application Number: 1 R43 DK61164-01
DUAL: HD

ZRG1 SSS-5 (10)
Review Group: CENTER FOR SCIENTIFIC REVIEW SEP

Meeting Dates: SRG: JUNE 2001 COUNCIL: SEPT/OCT 2001 DBL COMP
Requested Start Date: 11/01/2001

HIRSCHMAN, GORDON B, MENGBS
FOSTER-MILLER TECHNOLOGIES, INC
431 NEW KARNER ROAD
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Project Title: Foot Pressure and Shear Data Visualization System

SRG Action: Priority Score: 244
Human Subjects: 44-HS INV.-SRG CONCERNS
Animal Subjects: 10-NO LIVE VERTEBRATE ANIMALS INVOLVED
Gender: G4U-GENDER MAKE-UP UNKNOWN, SCIENTIFICALLY UNACCEPTABLE
Minority: M4U-MINORITY MAKE-UP UNKNOWN, SCIENTIFICALLY UNACCEPTABLE
Children: C4U-CHILDREN REPRESENTATION UNKNOWN, SCIENTIFICALLY UNACCEPTABLE
CLINICAL RESEARCH - NOT NIH-DEFINED PHASE III TRIAL

PROJECT YEAR	DIRECT COSTS REQUESTED	ESTIMATED TOTAL COST
01	52,655	119,415
TOTAL	52,655	119,415

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

RESUME AND SUMMARY OF DISCUSSION: This Phase I SBIR grant application is a feasibility study to initially develop 2-D software that will lead to eventual 3-D graphic visualization of shear and normal force stresses under the sole of the foot during ambulation. The software will initially be developed with data input from co-investigators at the Cleveland Clinic Foundation system. Major strengths of the proposal include the highly significant problem and need for improved clinical evaluation tools, the novel visualization techniques being proposed, and the collaboration with the Cleveland Clinic for the clinical evaluation data. Weaknesses of this complex project include concerns about the approaches and adequacy of available hardware, an insufficient discussion of the software integration with the hardware (Critique 1), and inadequately defined algorithms and discussion of their use for the clinical data interpretation (Critique 3). Concerns were expressed about the apparent approach to initially decide the relevant views to focus on rather than letting

the questions lead to the choice of views to study. Discussants pointed out that the proposed software development may be premature because shear force is not well understood and the lack of appropriate hardware. Other panel members considered the commercial potential to be good and commented that if the visualization system is not successful for intended goals, it could still be useful in the research laboratory. By the close of the discussion reviewer and discussant opinions remained in fairly close agreement with a range of high moderate to low moderate levels of enthusiasm for this worthwhile proposal.

DESCRIPTION (provided by applicant): Foot ulceration is a diabetic complication that results in over $1 billion worth of medical expenses per year in the United States alone. To better quantify the external forces involved in ulceration, researchers are developing new hardware systems that can measure both shear stress and vertical pressure. As these systems are commercialized, visualization software will be required for display and analysis of the 3-D stresses acting on the plantar surface. The proposed research will develop an advanced foot pressure and shear data visualization system, based on the innovative use of a deformed 2-D wire mesh to indicate stress, combined with more traditional vertical elevations and color-coding to indicate pressure. This new software will be adaptable to a variety of measurement systems, and will allow a clinician to see an accurate, 3-D representation of the maximum pressure and shear locations on the plantar surface. Also, novel analysis algorithms will be developed to identify areas where skin pressure and stress patterns (e.g., bunching, shearing, or stretching) are most likely to cause pathological consequences. Availability of this advanced software, in combination with new pressure/shear hardware measurement systems, will greatly improve the diagnosis, prevention, and treatment of foot ulcers in diabetic patients.

CRITIQUE 1:

1) SIGNIFICANCE: The problem of diabetic foot ulceration is no doubt important. Although it is widely believed that shear stresses are important it is not known whether or not, or to what extent shear stresses contribute to foot ulceration. Before one can assert that the development of software to visually describe and illustrate shear stresses is important one needs to be sure that this is the case. Further research needs to be performed using the instruments that are available. In addition to this limitation, shear stress measuring hardware has been available by the articles referenced in this grant submission since 1992. Why is it that none have been commercialized? Therefore one would be concerned that software would be developed without the available hardware. Finally, the availability of accurate reliable shear data at this time is the most important factor not whether or not it is graphically or visually appealing.

2) APPROACH: The investigators plan to utilize shear and normal force data that has been previously acquired using the shear force sensing system developed by the Cleveland Clinic Foundation. The initial software approach will be to utilize a planar 2-D representation of the data utilizing either a deformed wire mesh strategy or an arrow representation of local stress concentration which can be seen on page 23 of the proposal. They will then proceed to a 3-D approach that will simultaneously display shear and normal forces. The investigators do not describe a strategy that will be used to perform this.

They then propose to develop analysis algorithms with will allow stress and pressure patterns which is most likely associated with skin ulceration. The investigators once again do not indicate how they will do this. I am unaware of any data that will allow prediction of skin injury based upon shear and normal force measurement. They will then perform a clinical evaluation where they will show an expert clinical panel of foot/ankle specialists the data from 5 different clinical scenarios and have them provide feedback as to the usefulness and ease of interpretation from a clinical perspective. They will also be asked 6 specific questions that will require them to interpret the data objectively. When developing software for a specific user group it is important to get feedback from the group. This will enhance the development and also enhance the end product. One question that might be asked is the following; Since right now the utility of shear stresses is primarily a research application, are you really wanting to aim the software at a group of clinicians?

3) INNOVATION: The innovation of this device is moderate. There is no currently available software that will allow the simultaneous visualization of shear and normal forces. The software techniques that are proposed are not necessarily innovative but their use in this application are.

4) INVESTIGATORS: This is a strong group of investigators that have the clinical expertise as well as the necessary software development expertise to carry out the work.

5) ENVIRONMENT: Satisfactory

Human Subjects: There are no human subjects included in this application as human subject data will not be collected. However the first phase of the study does require the use of previously collected human data. I am not sure if those subjects would have allowed the use of the data for this application and therefore some type of human subjects approval for the use of this experimental data should probably be obtained.

OVERALL EVALUATION: The investigators have submitted a fairly well written proposal. They are submitting a proposal which suggests that they will be developing software that could be used with a variety of hardware devices that have been developed to measure shear stresses and normal forces. The devices have been developed are very different in their structure some of which have very few measuring cells. It is hard to envision the universality of the software and nowhere in the Phase I and II plans is there an effort made to do this. The utility of the software is only appropriate if the hardware is available. As noted above this hardware has not received wide acceptance. So is the software necessary? In addition the premise of the underlying necessity of the software is only accurate if shear stresses have a proven role in the underlying pathological process. This has not been done. Further research needs to be performed to validate this underlying presumption. Finally, They identify a "Task 4" which is to characterize the stress and pressure patterns most likely associated with skin ulceration. They do not define methods that will allow this to be accomplished. I am not aware of data that has shown that there are shear stress patterns that predict ulceration.

CRITIQUE 2:

1) SIGNIFICANCE: The purpose of this project is to develop a new software system that provides visualization of maximum pressure and maximum shear on the plantar surface of the foot. This is potentially significant because it would allow clinicians to better diagnose skin pressure patterns that would ultimately lead to ulcerations. The population targeted for this new technology is diabetic patients suffering from foot ulcerations. The investigators suggest that this group requires approximately 1 billion dollars worth of medical expenses each year in the United States.

2) APPROACH: This project involves a collaboration between Foster-Miller technologies in Albany, New York, and the Biomechanics Laboratory at the Cleveland Clinic Foundation in Cleveland, Ohio. Several research laboratories, including the group at the Cleveland Clinic, have developed instrumentation that allows one to measure shear stresses on the plantar surface of the foot. The Cleveland Clinic group will provide sample data to FMT, which they will use as the basis of their prototype development. FMT will develop two-dimensional and three-dimensional visualization prototype over the first few months of the project, which will then be evaluated by clinicians at the Cleveland Clinic Foundation. The software during Phase One will be developed using the visualization tool kit, an open source, object-oriented software platform for 3-D graphics and visualization. The user interface will be developed using TCL. Their plan is to develop a modular system that will allow commercialization by a third party, that has not yet been identified. Potentially, current distributors of foot-pressure sensing systems would be interested in this development.

3) INNOVATION: While sensor systems for estimating normal and shear pressures have existed for a number of years, there is no standard system for visualizing these data together. The proposed system would provide the first standard platform for enabling these visualizations.

4) INVESTIGATORS: Dr. Brian Davis and the staff at the Cleveland Clinic Foundation have been involved in the technical and clinical evaluation of diabetic foot ulceration for a number of years. This team is extremely well equipped to perform this study. While they have not yet shown results of their collaborations with the group at FMT, they have worked out a detailed schedule that seems reasonable for completion of this project. The Principal Investigator, Mr. Gordon Hirschman, has extensive experience in managing engineering projects.

5) ENVIRONMENT: The environment at the Cleveland Clinic Foundation is an excellent facility for evaluating the clinical utility of the software prototype. FMT has the appropriate resources to complete the project.

OVERALL EVALUATION: Clearly, excellent visualization can enhance the application of biomechanical data to the problem of foot ulceration in diabetes. The use of the VTK platform in TCL is a strength of the project. It is not clear if the investigators have examined the visualization techniques used in finite element analysis software for visualization of pressure and shear data. Perhaps these techniques could be adapted more directly than the techniques suggested in this proposal. Another strength of the proposal is the clinical evaluation at the Cleveland Clinic Foundation. Clearly, if this system

is to be used by clinicians, it must be evaluated and understandable by this group. I think this project has a good chance of success, and the investigators have demonstrated potential interest from third parties in eventually licensing and distributing the software. For this to be possible there will need to be a new interface developed to other commercial foot-pressure sensing systems.

CRITIQUE 3:

1) SIGNIFICANCE: The measurement of both shear and normal pressure on the plantar surface of the foot may prove to be an extremely useful tool for researchers and clinicians that aim to understand the etiology of foot ulcers. Considerable research must be done to develop the tools for the effective communication of this data.

Each sensor in the pressure sensor array placed under the foot requires six variables for its complete description (the location (x,y,z) and the orientation (thetaX, thetaY, thetaZ)) at every frame of the time series of data. This large data set must be presented in an effective manner to maximize the interpretation by the clinician or researcher.

The proposed system will develop visualization software for the display and analysis of the 3D stresses acting on the plantar surface of the foot. The visualization algorithm comprises an innovative use of a deformed 2D wire mesh to indicate stress, combined with more traditional vertical elevations and color-coding to indicate pressure.

2) APPROACH: The proposed visualization tool will focus on the presentation of the 6 degree of freedom force vector with respect to the matrix of sensors under the foot. The correspondence of the sensor array to the geometry of the plantar surface of the foot was not discussed but is presumably important for the interpretation of the data and should be discussed in a resubmission. The data may not be available, but if it were, it would require a straightforward extension to their software that should perhaps be included in anticipation of future technology.

I am confident that the investigators can read the data files and render 3D surfaces that represent the data precisely. I am concerned about the comment on page 25 that "non-linear mapping might better serve the clinician." This is rather dangerous because it explicitly assumes that the algorithm interprets the data better than the clinician, and that the clinician should be persuaded (through visualization techniques) to accept the predetermined interpretation. The algorithm, unfortunately is poorly described (perhaps poorly defined).

I have no doubt that this group can present the data in a form that the focus group will find pleasing. Well rendered 3D graphics surfaces are much "nicer" to look at than streams of data, or contour maps. More importantly, however, is the interpretation of the data by the clinician. Quantifying the ability of the clinician to interpret a "typical" (not contrived) data is presumably difficult and is the most important and least well addressed aspect of an otherwise well written proposal.

I would like a better explanation of the purpose of the clinical evaluation. How will the interpretation of the data be evaluated? I am assuming that the

"phantom" data are essentially simulated data that isolates five types of "patterns." Is the goal to have the clinician predict the correct pattern in the absence of any other clues? Will the clinician also be tested with the existing software. Existing software would provide answers to all questions on page 27. The innovativeness was meant to be interpreting the 6 dimensional nature of the data, not aspects of one or two degree of freedom data.

Many clinical biomechanics analysis software include the ability to present the 3D force vector (measured from a force platform) in relation to motion capture data of the foot. It is not clear to me that the presentation of an array of force vectors would not present the data equally as well as the methods proposed. This would require minimal modification of existing software (this may actually be the second method proposed but I am not sure).

The algorithm described for constructing the 3D surface is interesting and is worth presenting. If I am interpreting the technique correctly, the technique described may be equivalent to fitting a deformable surface to the 3D force vectors described in the preceding paragraph.

The computer algorithms to be developed for displaying the shear and pressure data are straightforward to implement and I anticipate that they will be readily completed early in the Phase I project. In several places in the proposal, the investigators have inserted apparently random comments. For example, on page 17. "In addition, since commercial hardware options are likely to provide sensors of differing sizes, it would be advantageous to utilize software that, based on sampling theory, could determine true peak shear and pressure values at every site on the plantar skin surface." It is not at all clear if they are proposing to do this, or in fact how it might be done. I am assuming that the concern of the investigators for manufacturers having sensors of different sizes relates to the challenges of spatially registering the pressure data to the geometry of the plantar surface of the foot. It sounds important, and if so, the investigators should expand on this comment.

Novel analysis algorithms will be developed to identify areas where skin pressure and stress patterns are most likely to cause pathological consequences. These computer algorithms for interpreting the shear and pressure data are unlikely to be so easy. I would like to see substantially more detail on the testing of these algorithms on simulated data sets and then on real data sets. Given that the visualization techniques may be modified to exaggerate the results from these interpretations, it is crucial that we know what the investigators are looking to find.

3) INNOVATION: Exceptional visualization tools for interpreting clinical data need to be developed. The visualization techniques proposed are novel and it is important that they be evaluated. If these visualization techniques allowed clinicians to be more effective at interpreting pressure data under the sole of the foot, then this tool will be innovative and important.

4) INVESTIGATORS: The investigators appear to be capable of performing the visualization work. The investigators may not have the experience to develop the analysis algorithms for interpreting the data in terms relevant to a clinician. Dr. Davis will be of tremendous assistance in this regard but it may require more than 5 percent effort on his part.

5) ENVIRONMENT: The environment is sufficient.

OVERALL EVALUATION: As with many visualization techniques, the implementation of a variety of strategies is much easier than quantifying the effectiveness of a particular strategy. I am very excited by the potential of this visualization strategy but, unfortunately, my enthusiasm was diminished by the lack of focus on determining if the intuitive visualization interpretations are actually correct.

The challenge of developing algorithms for interpreting this data in a clinically meaningful way and then adapting the renderings to emphasize the results from these algorithms needs to described much more clearly. The importance of visualization techniques for displaying complex time-series data is important and well worth pursuing.

HUMAN SUBJECT CONCERN: The face page of the application indicates that no human subjects will be used in Phase I. Reviewer 1 noted that previously collected human data will be used. There is inadequate information in the proposal to evaluate whether any human subject approval for the use of this data is required.

INCLUSION OF WOMEN, MINORITIES AND CHILDREN PLANS: These plans are not addressed and come into question because the details of the use of previously collected human subject data are unclear.

COMMITTEE BUDGET RECOMMENDATIONS: The study section concurred that the requested non-modular budget is appropriate for the proposed project.

MEETING ROSTER

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CENTER FOR SCIENTIFIC REVIEW
ZRG1 SSS-5 (10)
July 23, 2001 - July 24, 2001

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MEETING ROSTER

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July 23, 2001 - July 24, 2001

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.